K072591

Paieon
Realizing Cardiac Imaging

510(k) SUMMARY—CardiOp-B System

OCT 10 2007

Submitter Name:	Paieon Inc.
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Contact Person:	Ravit Barkama, MD
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Date Prepared:	Sept 12, 2007
Device Trade Name:	The CardiOp-B System
Device Common Name:	3D Vessel Analysis System
Classification Name:	3D Vessel Analysis System
Predicate Devices:	CardiOp-B cleared for marketing under K030139, QCA-CMS cleared under K993763 and CAAS QCA 3D cleared under K063344
Device Description:	The CardiOp-B System is an image acquisition and processing software system designed as an add-on to conventional X-ray angiography systems. The CardiOp-B system improves the output of coronary angiography by presenting a three-dimensional reconstruction of the stenosed vessel as well as quantitative cross-section information. The modifications to the CardiOp-B System which are the subject of this Special 510(K) include: 1. Bifurcation and side-branch analysis 2. Automatic calibration

Intended Use:	The CardiOp-B System is a software system that assists in the evaluation of coronary lesions by enabling the creation of 3D images of coronary vessel segments based on two to three 2D angiography images obtained from single plane angiography. CardiOp-B provides quantitative information regarding the calculated dimensions of arterial segments based on the 3D image. CardiOp-B is intended for use in real-time in the catheterization lab and off-line for post-procedural analysis. It is intended for use by clinicians, technicians and research personnel
Technological Characteristics Compared to Predicate Device:	The technological characteristics, e.g., overall design, principle of action, mode of operation, performance characteristics, etc., and the intended use of the Cardio-Op B system are substantially equivalent to the predicate devices cited above.
Performance Data:	Applicable performance testing was performed to evaluate the modifications to the CardiOp-B system. Testing included software validation and phantom performance evaluation. The test results were found to be acceptable as required by the respective test plans and protocols, demonstrating that the modified device performs according to its specifications. The test results did not raise new safety or effectiveness issues.
Conclusion:	The testing reported in this 510(K) establishes the modified CardiOp-B is substantially equivalent to the predicate devices and is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
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Rockville MD 20850

Paieon, Inc.
% Ravit Barkama, M.D.
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Paieon Medical Ltd.
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Rosh Haayin 48091
ISRAEL

OCT 10 2007

Re: K072591
Trade/Device Name: The CardiOp-B System
Regulation Number: 21 CFR 892.1600
Regulation Name: Angiographic x-ray system
Regulatory Class: II
Product Code: IZI
Dated: September 12, 2007
Received: September 14, 2007

Dear Dr. Barkama:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K072591

Device Name: **The CardiOp-B System**

Indications for Use:

The CardiOp-B System is a software system that assists in the evaluation of coronary lesions by enabling the creation of 3D images of coronary vessel segments based on two to three 2D angiography images obtained from single plane angiography. CardiOp-B provides quantitative information regarding the calculated dimensions of arterial segments based on the 3D image. CardiOp-B is intended for use in real-time in the catheterization lab and off-line for post-procedural analysis. It is intended for use by clinicians, technicians and research personnel.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072591

(Posted November 13, 2003)